UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JAMES R. LUPSKI,
CORNELIUS F. BOERKOEL III and HIROSHI TAKASHIMA

Appeal No. 2006-0298
Application No. 10/021,955

HEARD: February 7, 2006

Before ADAMS, MILLS and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

VACATUR AND REMAND TO THE EXAMINER

On consideration of the record, we find that this case is not susceptible to meaningful review and is thus not in condition for a decision on appeal. Accordingly, we vacate the pending rejections and remand the application to the examiner to consider the issues discussed herein and take appropriate action not inconsistent with the views expressed herein. Lest there be any misunderstanding, the term "vacate" in this context means to set aside or void. When the Board vacates an examiner's rejection, the rejection is set aside and

no longer exists. Cf. Ex parte Zambrano, 58 USPQ2d 1312, 1313 (Bd. Pat. App. & Int. 2001).

BACKGROUND

Claims 1-7, 35-40 and 42-61 are pending, claims 1, 35, 49 and 57 are representative of the claims on appeal, and are reproduced below.

1. A method of diagnosing myelinopathy in an individual, said myelinopathy resulting from a periaxin alteration in the individual, comprising the steps of:

obtaining a sample containing nucleic acid from said individual;

assaying said sample for an alteration in a periaxin polynucleotide, wherein said assaying step provides said diagnosis.

35. A method of detecting the presence or absence of a mutation associated with a myelinopathy, said myelinopathy resulting from a periaxin mutation in the individual, the method comprising:

(a) isolating a test nucleic acid from a subject, said test nucleic acid comprising a periaxin polynucleotide;

(b) comparing the test nucleic acid to a reference wild-type periaxin polynucleotide; and

(c) determining the differences between the test nucleic acid and the reference wild-type periaxin polynucleotide, wherein the differences are mutations in the periaxin polynucleotide of the subject, and wherein said detection of the presence or absence of the mutation is therein provided.

49. A method of detecting a polymorphism or mutation in a periaxin polynucleotide of an individual, comprising the steps of:

obtaining a sample comprising said periaxin polynucleotide from said individual;

assaying said periaxin polynucleotide for the polymorphism or mutation.

57. A method of identifying an individual suspected of having myelinopathy or being a carrier of myelinopathy, comprising the steps of:

obtaining from said individual a sample comprising nucleic acid; and

assaying said sample for an alteration in a periaxin polynucleotide, wherein the presence of the alteration identifies said individual as having periaxin-associated myelinopathy or being a carrier of periaxin-associated myelinopathy.

Claims 1-7, 35-40 and 42-61 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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The board serves as a board of review, not a de novo examination tribunal. See 35 U.S.C. § 6(b) ("The [board] shall, on written appeal of an applicant, review adverse decisions of examiners upon applications for patents."). The burden is on the examiner to set forth a prima facie case of nonpatentability. See In re Alton, 76 F.3d 1168, 1175, 37 USPQ2d 1578, 1581 (Fed. Cir. 1996).

We initially note that the claims in the application were subject to a restriction requirement, including the election of a single SEQ ID NO. and an election of species of a particular mutation. See Office Action mailed February 19, 2003, especially page 5. In response, Appellants elected "the species SEQ ID NO: 76 as the specific nucleotide sequence for examination purposes only,"

and also elected the species 247ΔC. See Response to Restriction Requirement and Preliminary Amendment, Stamped June 20, 2003, page 3. In response, the examiner stated that the election of SEQ ID NO: 76 "is not a species election rather, it is the election of a restricted SEQ ID No. corresponding to an elected group." Office action mailed July 23, 2003, page 2. The election of the specific SEQ ID NO. was made final on page 3 of the Office Action mailed April 30, 2004. Moreover, in the Final Rejection, mailed January 12, 2005, the examiner maintained the finality of the restriction to the specific SEQ ID NO., as well as the election of species, stating on page 10 that

> these sequences comprise patentably distinct SNPs or mutations of the periaxin gene. These SNPs or mutations result in patentably distinct periaxin sequences with different structures. These variant polynucleotides are structurally and functionally different. Hence the restriction requirement is still deemed proper and the finality is maintained.

Thus, it is clear that the subject matter before us is restricted to claims 1-7, 35-40 and 42-61 as they read on SEQ ID NO. 76, with the species of 247ΔC being elected for purposes of examination. With that in mind, we turn to the rejection of record.

Claims 1-7, 35-40 and 42-61 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement, as the containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In rejecting the claims, however, the examiner appears to have examined the full scope of the claims, and has not limited the analysis to the claims as they read on the elected group of SEQ ID NO. 76, nor as they read on the elected species 247ΔC. For example, as to the nature of the invention, the examiner states that the claims are drawn "to a method of detecting the presence or absence of any mutation in a periaxin polynucleotide and its association with any myelinopathy." Examiner's Answer, page 4. The examiner states further that "the specification has not established that a statistically significant association exists between all of the specific mutations disclosed in the specification, and any myelinopathy, or any specific myelinopathy, or that a predictable correlation can be made as to an association between any mutation in the periaxin gene and any myelinopathy or any specific myelinopathy." Id. at 5.

In addition, the rejection only briefly touches on the elected subject matter and the elected species, that is, the claims as they read on SEQ ID NO. 76 and 247ΔC, respectively. Thus, the examiner states in the Examiner's Answer that:

- The specification asserts that based on the common known methods in the art, mutations in other periaxin polynucleotide sequences (for example SEQ ID No. 76) could be detected. The specification discloses mutations in SEQ ID No. 1 and extrapolates the use of similar techniques to detect mutations in other periaxin polynucleotides (for example SEQ ID NO. 76). (Pages 4-5)

- It is clear from the teachings in Table-2, that the mere presence of an alteration in periaxin such as substitution or deletion is not indicative of myelinopathy. Further, with regard to the 2145T->A and 274 ΔC mutation in claim 36, and the R196X, C715X, or R82FSX96, the specification has provided no data as to whether these mutations are even associated with myelinopathy. (Page 10).

Thus, even when the rejection mentioned the elected subject matter, the analysis of the rejection made under 35 U.S.C. § 112, first paragraph, for lack of enablement, was not limited to the elected subject matter.

Upon return of the application, the examiner should reconsider the rejection in view of the restriction requirement and the election of species. If the examiner is withdrawing the restriction requirement and the election of species, that fact should be stated for the record. If the examiner is not withdrawing the restriction requirement and the election of species, the analysis accompanying the rejection should be limited to that subject matter, i.e., the claims as they read on SEQ ID NO. 76 and 247ΔC. In making that rejection, the record should establish the relationship between SEQ ID NO. 76 and the other claimed SEQ ID Nos, and why any enablement provided for the other SEQ ID NO.s does not apply to the elected SEQ ID NO. The same should also be done for the elected species 247ΔC.

Finally, the examiner's analysis is focused on a method as set forth in claim 1, and does not adequately address the methods as set forth in claims 35 and 49.

Claim 1 is drawn to a method of diagnosing myelinopathy in an individual. Claim 35 is drawn to a method of detecting the presence or absence of a mutation associated with a myelinopathy, and claim 49 is drawn to a method of detecting a polymorphism or a mutation a periaxin polynucleotide of an individual. All that is required by those two claim is comparison of the test

nucleic acid comprising a periaxin polynucleotide to a wild-type periaxin polynucleotide, and determining the differences between the two polynucleotides to find a mutation and/or a polymorphism.

The enablement rejection focuses on the association between a mutation and a myelinopathy, see, e.g., Examiner's Answer, page 5, and the use of the association as a diagnostic tool. Claims 35 and 49 do not, however, require any diagnosis. Thus, upon return of the case, the examiner should consider the subject matter of independent claims 35 and 49 separately, and if a rejection is appropriate, clearly indicate how the rejection applies to the subject matter of those claims.

FUTURE PROCEEDINGS

The case is being returned to the jurisdiction of the examiner for further action not inconsistent with this decision.

If prosecution is resumed, we state that we are not authorizing a Supplemental Examiner's Answer.

VACATED and REMANDED

Donald E. Adams)
Administrative Patent Judge)
)
Demetra J. Mills) BOARD OF PATENT
Administrative Patent Judge) APPEALS AND
)
Lora M. Green) INTERFERENCES
Administrative Paten Judge)

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